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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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10/840,205

05/06/2004

Christopher E. Banas

6006-157

7254

7590

04/27/2006

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EXAMINER

BARRETT, THOMAS C

ART UNIT

PAPER NUMBER

3738

DATE MAILED: 04/27/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

10/840,205

Applicant(s)

BANAS ET AL.

Examiner

Thomas C. Barrett

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☐ Responsive to communication(s) filed on ____.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-16 is/are pending in the application.
- 4a) Of the above claim(s) ____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) ____ is/are allowed.
- 6) ☒ Claim(s) 1-16 is/are rejected.
- 7) ☐ Claim(s) ____ is/are objected to.
- 8) ☐ Claim(s) ____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on ____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. ____.
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. ____ |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| Paper No(s)/Mail Date <u>1-06</u> . | 6) <input type="checkbox"/> Other: ____ |

DETAILED ACTION

Specification

The lengthy specification has not been checked to the extent necessary to determine the presence of all possible minor errors. Applicant's cooperation is requested in correcting any errors of which applicant may become aware in the specification.

Information Disclosure Statement

The information disclosure statement filed January 3, 2006 fails to comply with 37 CFR 1.98(a)(2), which requires a legible copy of each cited foreign patent document; each non-patent literature publication or that portion which caused it to be listed; and all other information or that portion which caused it to be listed. It has been placed in the application file, but the information referred to therein has not been considered. The copies must be provided even if the patent, publication, pending U.S. application or other information was previously submitted to, or cited by, the Office in an earlier application, unless the earlier application is properly identified in the information disclosure statement and is relied on for an earlier effective filing date under 35 U.S.C. **120**. However, the present application only claims **priority** to provisional application 60/468,425. The Applicant fails to disclose how the other cited applications and patents are related in either the IDS or the specification.

Drawings

The drawings are objected to under 37 CFR 1.83(a). The drawings must show every feature of the invention specified in the claims. Therefore, the ***suturing openings*** as cruciform or generally Y-shaped slots, and the thickness of the undulating regions as less than that of the non-undulating regions, must be shown or the feature(s) canceled from the claim(s). No new matter should be entered.

Corrected drawing sheets in compliance with 37 CFR 1.121(d) are required in reply to the Office action to avoid abandonment of the application. Any amended replacement drawing sheet should include all of the figures appearing on the immediate prior version of the sheet, even if only one figure is being amended. The figure or figure number of an amended drawing should not be labeled as "amended." If a drawing figure is to be canceled, the appropriate figure must be removed from the replacement sheet, and where necessary, the remaining figures must be renumbered and appropriate changes made to the brief description of the several views of the drawings for consistency. Additional replacement sheets may be necessary to show the renumbering of the remaining figures. Each drawing sheet submitted after the filing date of an application must be labeled in the top margin as either "Replacement Sheet" or "New Sheet" pursuant to 37 CFR 1.121(d). If the changes are not accepted by the examiner, the applicant will be notified and informed of any required corrective action in the next Office action. The objection to the drawings will not be held in abeyance.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 1-4, and 13-15 are rejected under 35 U.S.C. 102(b) as being anticipated by Palmaz et al (WO 01/74274 A2). Palmaz et al discloses an implantable medical graft, comprising: a. a generally tubular body member comprising a film selected from the group consisting of metallic and pseudometallic materials (page 17, lines 1-7); and b. at least a portion of the body member having a plurality of circumferential undulations formed in walls of the body member and microperforations (e.g. Figs. 2-3 and 8A-8C).

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 5, 12 and 16 are rejected under 35 U.S.C. 103(a) as being unpatentable over Palmaz et al (WO 01/74274 A2) as above in view of Van Schie et al (6,974,471 B2). Palmaz et al discloses an implantable medical graft as above. However, Palmaz et al does not disclose at least one suture member integrally extending along the longitudinal axis and through suture holes. Van Schie et al teaches an implantable

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medical graft comprising at least one suture member integrally extending along the longitudinal axis and through suture holes (e.g. Fig 1). It would have been obvious to one having ordinary skill in the art at the time the invention was made to combine the teaching of at least one suture member integrally extending along the longitudinal axis and through suture holes, as taught by Van Schie et al, to an implantable medical graft as per Palmaz et al, in order so that "the device can be curved insitu to fit the curved lumen" as found in Van Schie et al (col. 1, lines 44-52).

Claims 6-10 are rejected under 35 U.S.C. 103(a) as being unpatentable over Palmaz et al (WO 01/74274 A2) in view of Van Schie et al (6,974,471 B2) as above, and in further view of Kula et al (6,325,825 B1). Palmaz/ Van Schie discloses an implantable medical graft as above. However Palmaz/ Van Schie does not disclose the thickness of the undulating regions as less than that of the non-undulating regions. Kula et al teaches an implantable medical graft having thicker ends, which correspond to the non-undulating regions of Palmaz/ Van Schie (col. 4, lines 60-66). It would have been obvious to one having ordinary skill in the art at the time the invention was made to combine the teaching of an implantable medical graft having thicker ends, as taught by Kula et al, to an implantable medical graft as per Palmaz/ Van Schie, in order to "protect the artery and any plaque from abrasion that may be caused by the stent 10 ends during insertion of the stent 10. The modification also may provide increased radio-opacity at the ends of the stent 10. Hence it may be possible to more accurately locate the stent 10 once it is in place in the body" as found in Kula et al (col. 4, lines 60-66).

Regarding claim 7, Palmaz et al in view of Van Schie et al in further view of Kula et al fail to disclose the specific thicknesses of the claimed regions. However, Palmaz et al discloses that the thickness of the microperforated material is approximately 10 micrometers (page 21, lines 13-14). Palmaz et al also discloses that the undulations may be formed by a “subtractive” method (Fig. 10). The reduction of the undulation region relative to the non-undulated region would result in a thickness of the thinner region **about** 3-7 micrometers.

Furthermore, regarding claims 9-10, Palmaz et al in view of Van Schie et al in further view of Kula et al fail to disclose the suturing openings as cruciform or generally Y-shaped slots. At the time the invention was made, it would have been obvious to a person of ordinary skill in the art to make the slots these shapes. Applicant has not disclosed that these shapes provides an advantage, is used for a particular purpose, or solve a stated problem. One of ordinary skill in the art, furthermore, would have expected Applicant's invention to perform equally well with either the holes of Van Schie et al or the claimed slots because both allow for the passage of sutures. Therefore, it would have been obvious to one of ordinary skill in the art to modify the cited references to obtain the invention as specified in claims 9 and 10. Please note that the Applicant may have intended to claim the microperforations as cruciform or generally Y-shaped slots.

Claim 11 is rejected under 35 U.S.C. 103(a) as being unpatentable over Palmaz et al (WO 01/74274 A2) as above in view Banas et al (5,749,880). Palmaz et al discloses an implantable medical graft as above. However Palmaz et al does not

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disclose the implant having barbs. Banas et al teaches an implantable medical graft having projecting barb members (col. 14, lines 48-54). It would have been obvious to one having ordinary skill in the art at the time the invention was made to combine the teaching of projecting barb members, as taught by Banas et al, to an implantable medical graft as per Palmaz et al, in order to aid in anchoring to the target blood vessel wall, as in Banas et al (col. 14, lines 48-54).

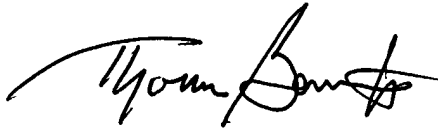
Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Thomas C. Barrett whose telephone number is (571) 272-4746. The examiner can normally be reached Tuesday-Friday between 9:00 A.M. and 6:00 P.M.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Corrine McDermott can be reached on (571) 272-4754. The fax phone numbers for the organization where this application or proceeding is assigned are (703) 872-9306 for regular communications.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

A handwritten signature in black ink, appearing to read "Thomas Barrett", with a stylized flourish at the end.

Thomas Barrett
Examiner
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